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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT : Kreek et al.

SERIAL NO. : 09/905,186 EXAMINER : Sakelaris, Sally

FILED : July 13, 2001 ART UNIT : 1634

FOR : ALLELES OF THE HUMAN ORPHANIN FQ/NOCICEPTIN RECEPTOR GENE, DIAGNOSTIC METHODS USING SAID ALLELES, AND METHODS OF TREATMENT BASED THEREON

CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.8

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RESPONSE TO RESTRICTION REQUIREMENT

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

Dear Sir:

The following reply is responsive to the Requirement for Restriction mailed March 25, 2003, due for a response on April 25, 2003.

In the Requirement for Restriction, the Examiner requested election of one of the following groups:

Group I; claims 31-47, and 59-61, drawn to a variant allele of a human orphanin FQ/nociceptin receptor gene, cloning vector, expression vector, and unicellular host, kit containing primers and to nucleic acids.

Group II; claims 48-58, drawn to a method for determining a susceptibility to an addictive disease or pain, or to determine a therapeutically effective amount of a therapeutic agent by genotyping.

Applicants hereby elect to prosecute the invention of Group I, claims 31-47 and 59-61 drawn to a variant allele of a human orphanin FQ/nociceptin receptor gene, cloning vector, expression vector, and unicellular host, kit containing primers and to nucleic acids, with traverse.

The Examiner has also noted that an election must be made to one of the variants that falls within SEQ ID NO: 1 if Group I were elected. Applicants hereby elect SEQ ID NO: 1 and the variant that is designated as C510T, and the corresponding primers and probes that correspond to the C510T variant for use in amplification to comprise the kits, with traverse.

Applicants respectfully request reconsideration of the Requirement for Restriction, or in the alternative, modification of the Restriction Requirement to allow prosecution of more than one group of Claims, or in the alternative, more than one variant and corresponding primers and probes designated by the Examiner in the present Application, for the reasons provided as follows.

Under 35 U.S.C. §121 "two or more independent and distinct inventions ... in one Application may ... be restricted to one of the inventions." Inventions are "'independent'" if "there is no disclosed relationship between the two or more subjects disclosed" (MPEP 802.01). The term "'distinct'" means that "two or more subjects as disclosed are related ... but are capable of separate manufacture, use or sale as claimed, AND ARE PATENTABLE OVER EACH OTHER" (MPEP 802.01) (emphasis in original). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification
2. Separate status in the art; or
3. Different field of search.

Further, under Patent Office Examining Procedures, "[i]f the Search and Examination of an entire Application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803, Rev. 8, May 1988) (emphasis added).

Applicants respectfully submit that the groups designated by the Examiner fail to define compositions and methods, with properties so distinct as to warrant separate Examination and Search. The claims of Group I are drawn to a variant allele of a human orphanin FQ/nociceptin receptor gene, cloning vector, expression vector, and unicellular host, kit containing primers and to nucleic acids. The claims of Group I are fundamentally related to the claims of Group II, drawn to a method for determining a susceptibility to an addictive disease or pain, or to determining a therapeutically effective amount of a therapeutic agent by genotyping, which Applicants respectfully point out, could not be achieved without the variants identified by Applicants and claimed in the presently pending claims of Group I and II. The search for any of the methods separately classified by the Examiner as the invention of Group II would require an additional search of the **identical** sequences wherein the claims of Group I are classified, thus resulting in a duplicate search for the same material. It was Applicants own research which identified the variants of the orphanin FQ/nociceptin receptor gene and their own work which identified the potential for their utility. Therefore, a search on the sequences of the variants would in all likelihood result in identification of references pointing to their potential utility as well.

Thus, Applicants submit that the Search and Examination of Group I with Group II can be made without serious burden, and therefore the Examiner must examine all of the claims of the Application on the merits.

The Examiner's assertions to the contrary notwithstanding, Applicants respectfully submit that conjoint examination and inclusion of all of the Claims of the present Application would not present an undue burden on the Examiner, and accordingly, withdrawal of the Requirement for Restriction, or, at the least, modification to include more than one variant identified in claim 31 is respectfully requested. In particular, Applicants request reconsideration for inclusion of 2 additional variants that fall within the coding region of the human orphanin FQ/nociceptin receptor gene, that are identified in claim 31 as A804G and C1026T with the above-noted and elected variant designated as C510T. Based on the sequences disclosed that cover C510T (SEQ ID NO: 7), A804G (SEQ ID NO: 9) and C1026T (SEQ ID NO: 10), Applicants assert that a search on these three variants, which all fall within the coding region, would not present an undue burden on the Examiner.

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